REMARKS

Claims 1, 2, 4, 5, and 8 – 13 are currently pending. In the Office Action of February 17, 2009, each of Claims 1, 2, 4, 5, and 8 – 13 were rejected as allegedly obvious over U.S. Patent No. 6,740,341 to Holt et al. ("Holt") taken in combination with U.S. Patent No. 6,565,877 to Mukherji et al. ("Mukherji").

Claims 1, 2, 9, 10 and 11 are amended to more particularly point out and distinctly define the claimed subject matter by specifying, among other things, that the micropellets are granular. Support for the amendment with regard to the granularity of the micropellets may be found at least in the first paragraph of page 4 of the specification. Support for the other minor clarifying amendments may be found throughout the specification. No new matter is entered into the case by the amendment.

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the following remarks.

A. Claims 1, 2, 4, 5, and 8-13 are Patentably Distinct Over the Cited References.

Claims 1, 2, and 9 are independent claims directed to a taste masking composition calling for, among other things, micropellets including a core of one or more antibiotic particles coated with an inner cellulosic polymeric coating which in turn is coated with an enteric coating comprising an enteric coating polymer.

Enteric coating polymers are used to control the release of the antibiotic medication so that the antibiotic is generally not released into gastric fluid medium until the micropellets reach the small intestine. In other words, an enteric coating helps avoid release of the antibiotic medication in the stomach. An enteric coating is therefore generally soluble at higher pHs than those typically encountered in the stomach, and is generally insoluble at pHs typically seen in the stomach.

Holt is inapplicable because, among other things, it is directed to rapid release taste-masked formulations, where the active ingredient is released in a patient's stomach. Holt teaches that "the taste masking layer must be capable of rapidly exposing the spacing layer when the formulation reaches the patient's stomach." (Holt, Column 2, Lines 38-40). Holt explicitly directs

that the taste masking layer should be capable of rapidly dissolving in the stomach of a patient. (Holt, Column 6, Lines 12-13). Holt then goes on to provide examples using EUDRAGIT E-100 as the taste masking layer, a material known to be insoluble in saliva in the mouth but quite soluble in the acid environment of the stomach. In this regard, the labels, "taste masking" or "delayed release" are a bit misleading as applied to EUDRAGIT E-100 because it does not behave like an enteric coating. The "delay" of release or "masking" provided by EUDRAGIT E-100 is simply a delay of release of the covered material until it reaches the stomach, not a delay until it reaches the small intestine. Such a polymer is not known in the art to be an enteric coating because, once again, it releases in the stomach, not in the intestine. Holt therefore very plainly does not teach, disclose, or suggest use of an enteric coating layer according to Applicants' claims and cannot lawfully be said to render Applicants' claims obvious to a person of ordinary skill. .

The inclusion of Mukherji in this combination is ineffectual, as it does not remedy the deficiencies of Holt or somehow suggest the subject matter of Applicants' claims.

Like Holt, Mukherji fails to teach, disclose, or suggest taste-masked micropellets configured according to Applicants' claims. Mukherji teaches a drug-polymer matrix in which enteric materials are mixed with the active ingredient to make a "fine dispersion." This hardly teaches micropellets with active ingredient-containing cores onto which multiple discrete layers are applied, including an outer "enteric" coating. Therefore, Mukherji fails to provide all of the elements and limitations of the present claims, and cannot reasonably be said to render the claims obvious.

Furthermore, Mukherji cannot fairly be said to suggest replacing the stomach-release coating of Holt with an enteric material, as this would teach away from, and in fact eviscerate, the teachings of Holt with regard to the medication being released in the patient's stomach in Holt's formulation. The teachings of Mukherji are essentially incompatible with those of Holt regarding the structure of pharmaceuticals in the respective patents because Holt wants the medicine released in the stomach and Mukherji wants it released later in the intestine. A person of ordinary skill in the art would have no reasonable motivation to combine these two disparate references, since the proposed combination would drastically alter the principle of operation of Holt's composition. If

Holt were modified with Mukherji as suggested in the Office Action, the formulation would be rendered inoperable for its intended purpose. See *In re Gordon*, 733 F.2d 900, 221 USPQ 11125 (Fed. Cir. 1984). Thus, the combination of Holt and Mukherji cannot lawfully be used to support an obviousness rejection.

With regard to Independent Claim 2, neither Holt nor Mukherji disclose the claimed granular micropellets having an enteric coating for at least the reasons discussed above. Therefore, no combination of the references could fairly be said to render Claim 2 obvious, either. The same is true for Claim 9.

Accordingly, the cited references do not create any *prima facie* case of obviousness with respect to independent Claims 1, 2, and 9, or any claim dependent thereupon. The reasons for this are twofold: first, neither of the references nor their combination teaches, discloses, or suggests all of the elements of the present claims, and second, the proposed combination would impermissibly alter the principle of operation of the primary reference and there is not reasonable basis to assert that any person of skill would be motivated to combine them in any way in an effort to make a composition according to Applicants' claims. Therefore, Applicants once again urge reconsideration and allowance of Claims 1, 2, 5, and 8-13 at the earliest possible convenience.

CONCLUSION

In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a Notice of Allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

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